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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/609,383	07/03/00	HEINEGARD D	06803.0008

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EXAMINER	
HUYNH, P	
ART UNIT	PAPER NUMBER
1644	5

DATE MAILED: 05/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/609,383	HEINEGARD ET AL.	
	Examiner	Art Unit	
	" Neon" Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. **Please note** the location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). This application is complied with Sequence rules.

3. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

4. Claims 1-35 are pending in instant application.

Election/Restrictions

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-8, drawn to isolated or recombinant polypeptide from chondrocyte-containing tissues encoding by SEQ ID NO: 2, classified in Class 530, subclass 300.

   II. Claims 1-8, drawn to an analog of chondrocyte-containing tissues encoding by SEQ ID NO: 2, classified in Class 530, subclass 300.

   III. Claims 1-8, drawn to a homolog of chondrocyte-containing tissues encoding by SEQ ID NO: 2, classified in Class 530, subclass 300.

   IV. Claims 9-18, drawn to a purified or isolated polynucleotide of CILP encoding by SEQ ID NO: 1, vector, host cells, classified in Class 536, subclass 23.5, Class 435, subclass 69.1, Class 435, subclass 252.3.

V. Claims 9-18, drawn to an analog of purified or isolated polynucleotide of CILP encoding by SEQ ID NO: 1, vector, host cells, classified in Class 536, subclass 23.5, Class 435, subclass 69.1, Class 435, subclass 252.3.

VI. Claims 9-18, drawn to a homolog of isolated polynucleotide of CILP encoding by SEQ ID NO: 1 , vector, host cells, classified in Class 536, subclass 23.5, Class 435, subclass 69.1, Class 435, subclass 252.3.

VII. Claim 19, drawn to an oligonucleotide, classified in Class 536, subclass 24.31.

VIII. Claims 20-24 and 34-35, drawn to an antibody that binds to a CILP, pharmaceutical composition and kit, classified in Class 530, subclass 387.1.

IX. Claims 20-24 and 34-35, drawn to an antibody that binds to an analog of CILP pharmaceutical composition and kit, classified in Class 530, subclass 387.1.

X. Claims 20-24 and 34-35, drawn to an antibody that binds to a homolog of CILP pharmaceutical composition and kit, classified in Class 530, subclass 387.1.

XI. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is osteoarthritis using polypeptide, classified in Class 424, subclass 130.1.

XII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is rheumatoid arthritis using polypeptide, classified in Class 424, subclass 130.1.

XIII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is crystal deposit arthritis using polypeptide, classified in Class 424, subclass 130.1.

XIV. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is psoriatic arthritis using polypeptide, classified in Class 424, subclass 130.1.

XV. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is reactive arthritis using polypeptide, classified in Class 424, subclass 130.1.

XVI. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is osteoarthritis using an analog of CILP, classified in Class 424, subclass 130.1.

XVII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is rheumatoid arthritis using an analog of CILP, classified in Class 424, subclass 130.1.

XVIII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is crystal deposit arthritis using an analog of CILP, classified in Class 424, subclass 130.1.

XIX. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is psoriatic arthritis using an analog of CILP, classified in Class 424, subclass 130.1.

XX. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is reactive arthritis using an analog of CILP, classified in Class 424, subclass 130.1.

XXI. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is osteoarthritis using a homolog of CILP, classified in Class 424, subclass 130.1.

XXII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is rheumatoid arthritis using a homolog of CILP, classified in Class 424, subclass 130.1.

XXIII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is crystal deposit arthritis using a homolog of CILP, classified in Class 424, subclass 130.1.

XXIV. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is psoriatic arthritis using a homolog of CILP, classified in Class 424, subclass 130.1.

XXV. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is reactive arthritis using a homolog of CILP, classified in Class 424, subclass 130.1.

XXVI. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is osteoarthritis using an antibody that binds to CILP, classified in Class 424, subclass 130.1.

XXVII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is rheumatoid arthritis using an antibody that binds to CILP, classified in Class 424, subclass 130.1.

XXVIII. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is crystal deposit arthritis using an antibody that binds to CILP, classified in Class 424, subclass 130.1.

XXIX. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is psoriatic arthritis using an antibody that binds to CILP, classified in Class 424, subclass 130.1.

XXX. Claims 25-27, drawn to a method of treating individuals with a joint disease wherein the joint disease is reactive arthritis using an antibody that binds to CILP, classified in Class 424, subclass 130.1.

XXXI. Claims 28-30 and 32-33, drawn to a method of detecting osteroarthritis using antibody, classified in Class 435, subclass 7.92.

XXXII. Claims 28-29, 31-33, drawn to a method of detecting messenger RNA encoding CILP or a portion thereof, classified in Class 435, subclass 91.2.

6. The inventions are distinct, each from the other because of the following reasons:

Groups I-X (polypeptide, analog, oligonucleotide and antibody) are different and distinct products. They differ with respect to their physiochemical properties, structures, mode of action and one cannot be substituted for the other. Therefore they are patentably distinct.

Groups (I-X) and (XI-XXXII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the polypeptide protein can be used as an immunogen to produce antibodies as well as therapeutic methods claimed.

In the instant case, the antibody can be used as the therapeutic methods as claimed and diagnostic/screening assays. Therefore, they are patentably distinct.

In the instant case, the oligonucleotide can be used to produce the proteins of interest as well as screening assays as claimed.

Groups XI-XXXII are different method of treating different diseases wherein the specific diseases differ with respect to their etiologies and therapeutic endpoints with different products which differ with respect to their physiochemical properties, structures, and mode of action. Therefore, the restriction has been set forth for each as separate groups, irrespective of the format of the claims.

7. Because these inventions are distinct for the reasons given above and the search is not co-extensive and divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
May 16, 2001

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